INSTRUCTIONS FOR USE FOR:

BIFURCATED ENDOPROSTHESIS

AORTIC AND ILIAC EXTENDERS
(For Use With The EXCLUDER Bifurcated Endoprosthesis)

en
English

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INSTRUCTIONS FOR USE

EXCLUDER EXTENDER ENDOPROSTHESES-AORTIC AND ILIAC

(FOR USE WITH THE EXCLUDER BIFURCATED ENDOPROSTHESIS)

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

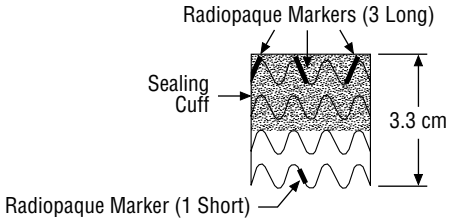
DESCRIPTION

The EXCLUDER Extender Endoprostheses (Aortic and Iliac) are devices to be used after deployment of the EXCLUDER Bifurcated Endoprosthesis.

Aortic Extender Endoprosthesis

The Aortic Extender Endoprosthesis (Aortic Extender) provides an extension of approximately 1.6 cm of the leading (proximal) end of the Trunk-Ipsilateral Leg Endoprosthesis (Trunk). This extension also allows a minimum of approximately 1.6 cm overlap with the Trunk, and can be overlapped with the Trunk at increasing length, until completely seated within the Trunk if necessary. This allows for customization of extender length based on patient anatomy and physician preference. The graft material is expanded polytetrafluoroethylene and fluorinated ethylene propylene (ePTFE and FEP), and is supported by nitinol wire along its external surface. An ePTFE/FEP sealing cuff is located near the proximal end of the endoprosthesis (Figure 1). An ePTFE/FEP sleeve is used to constrain the endoprosthesis on the leading end of the delivery catheter (Figures 2A and 2B). Deployment of the Aortic Extender initiates from the trailing (trunk) end and proceeds toward the leading (aortic) end of the endoprosthesis and delivery catheter. Following deployment, the ePTFE/FEP sleeve remains in situ between the endoprosthesis and the vessel wall.

FIGURE 1: AORTIC EXTENDER ENDOPROSTHESIS*



Aortic Extender Radiopaque Markers (4 total)

- Three (3) long markers at the proximal or top end
- One (1) short marker at the distal or bottom end

FIGURE 2A: EXCLUDER EXTENDER ENDOPROSTHESIS DELIVERY CATHETER

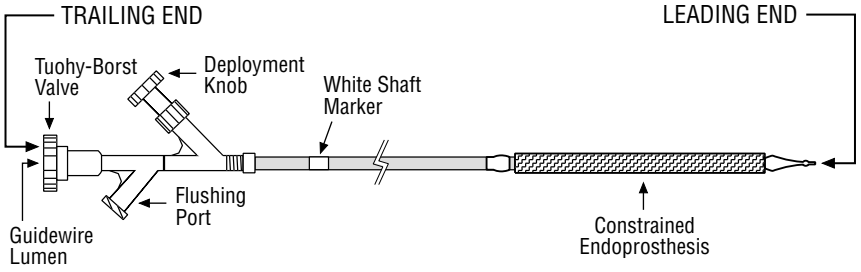


FIGURE 2B: CONSTRAINED EXCLUDER EXTENDER ENDOPROSTHESIS (AORTIC EXTENDER)

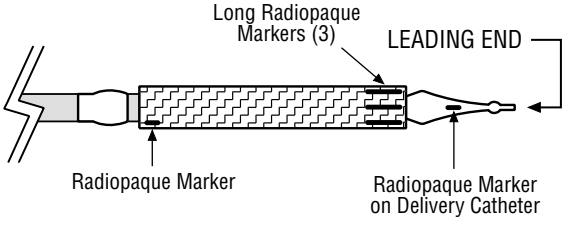
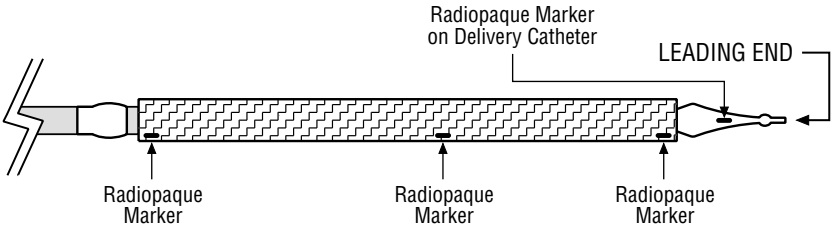


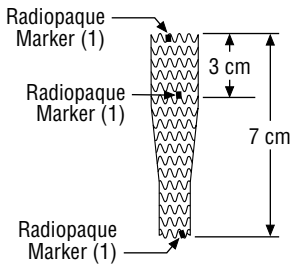
FIGURE 2C: CONSTRAINED EXCLUDER EXTENDER ENDOPROSTHESIS (ILIAC EXTENDER)



Iliac Extender Endoprosthesis

The Iliac Extender Endoprosthesis (Iliac Extender) provides an extension of up to 4 cm of either the ipsilateral or contralateral limb. The extender component can be placed at variable extension lengths from 4 cm to 0 cm for a complete overlap within the iliac leg component allowing customization of extender treatment length based on patient anatomy and physician preference. The graft material is ePTFE/FEP, and is supported by nitinol wire along its external surface. A radiopaque marker is located 3 cm from the proximal or top end (Figures 2C and 3). This marker denotes the recommended minimum overlap with the ipsilateral or contralateral limb of the EXCLUDER Bifurcated Endoprosthesis. An ePTFE/FEP sleeve is used to constrain the endoprosthesis on the leading end of the delivery catheter (Figures 2A and 2C). Deployment of the Iliac Extender initiates from the leading (aortic) end and proceeds toward the trailing (iliac) end of the delivery catheter. Following deployment, the ePTFE/FEP sleeve remains in situ between the endoprosthesis and the vessel wall.

FIGURE 3: ILIAC EXTENDER ENDOPROSTHESIS*



Iliac Extender Radiopaque Markers (3 total)

- Two (2) end markers: One (1) at each end
- One (1) marker located 3 cm below the proximal end

* Note: All dimensions in Figures 1 and 3 are nominal.

INTENDED USE

The EXCLUDER Extender Endoprostheses (Aortic and Iliac) are intended to be used after deployment of the EXCLUDER Bifurcated Endoprosthesis. These extensions are intended to be used when additional length and/or sealing for aneurysmal exclusion is desired in patients who have appropriate anatomy.

CONTRAINDICATIONS

Known contraindications include, but are not limited to:

- Significant thrombus at the arterial implantation site
- Aortic Extender: Proximal aortic neck angulation > 60°
- Ilio-femoral access vessel morphology should be compatible with vascular access techniques, devices and accessories.

WARNINGS

- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- Do not advance the device outside of the sheath.
- Do not attempt to withdraw the undeployed endoprosthesis through the 18 Fr or 12 Fr introducer sheath valve. The sheath and catheter must be removed together.
- Do not rotate either delivery catheter. Catheter breakage or premature deployment may occur.
- Do not attempt to reposition the endoprosthesis after deployment has been initiated. Vessel damage or endoprosthesis misplacement may result.
- Do not attempt to advance the Aortic Extender through the 12 Fr introducer sheath. The Aortic Extender is designed for the 18 Fr sheath.

- Do not continue to advance any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or delivery catheter. Stop and assess the cause of resistance. Vessel or catheter damage may occur.
- Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
- Do not obstruct significant renal or mesenteric arteries. Vessel occlusion may occur (exception — planned occlusion of internal iliac arteries).
- Do not use delivery catheter for high pressure fluid injections.

PRECAUTIONS

- Do not resterilize; for single use only.
- Do not use if damaged or if sterile barrier has been compromised.
- Do not use after the “use by” (expiration) date printed on the label.

ADVERSE EVENTS

Adverse events that may require intervention include, but are not limited to: infection; bleeding at the site of catheter and sheath placement; lymph fistula; local neurologic damage; ilio-femoral vascular access anatomy complications including vascular trauma, occlusion, arteriovenous fistula, thrombosis and/or pseudoaneurysm; trauma to the aortic or ilio-femoral vessel wall, including dissection, perforation, rupture or erosion; fever and localized inflammation; microembolization and macroembolization; bowel ischemia; aortoenteric fistula; acute hepatic failure; renal failure or other renal complications; respiratory complications; congestive heart failure; arrhythmia; myocardial infarction; paraplegia; stroke; incomplete device component deployment; improper endoprosthesis component placement; endoprosthesis component migration; stent fracture; graft material failure or dilatation, erosion, puncture, separation of graft material from stent; endoprosthesis occlusion; endoprosthesis infection; endoleak; continued aneurysm enlargement; aneurysm rupture and death.

SUMMARY OF CLINICAL STUDIES

OBJECTIVES

The primary objective of the clinical study was to demonstrate that the EXCLUDER Bifurcated Endoprosthesis is a safe and effective alternative to open surgical repair in the primary treatment of infrarenal abdominal aortic aneurysms. Safety was determined by demonstrating that the EXCLUDER Bifurcated Endoprosthesis subjects would have a total proportion of major adverse events that is less than the subjects treated with open surgical repair as evaluated through one year follow-up. Effectiveness was based on exclusion of the aneurysm including the absence of an endoleak, the absence of aneurysm enlargement (≥ 5 mm), and the absence of major device efficacy adverse events evaluated through one year follow-up. Secondary objectives included an assessment of clinical benefit and quality-of-life measures.

STUDY DESIGN

This prospective, non-randomized, multi-center clinical study was designed to compare patients treated with endovascular repair to an open surgical repair control group. The control group included patients whose vascular anatomy (proximal aortic neck length, proximal neck angulation, and arterial implantation site condition) may not have been suitable for endovascular AAA repair. The planned ratio of EXCLUDER Bifurcated Endoprostheses to control subjects was approximately 2:1. Follow-up evaluations were scheduled for pre-discharge, 1-month, 3-months (if endoleak at 1-month), 6-months and 12-months. An independent Core Lab facility reviewed CT scans and abdominal x-rays to assess aneurysm diameter changes, device and relative component migration, device integrity (wire and graft) and the presence and type of endoleaks.

DESCRIPTION OF SUBJECTS

Nineteen U.S. sites enrolled 235 EXCLUDER Bifurcated Endoprostheses and 99 control subjects. Given the epidemiology of AAA and surgical repair, males predominated over females (83% compared to 17%). The selection criteria for the study were based on enrolling subjects with the appropriate anatomy for endovascular repair. A total of 31 females were treated with EXCLUDER Bifurcated Endoprostheses and 26 with open surgical repair. For subjects treated with EXCLUDER Bifurcated Endoprostheses, there were no differences between males and females for results through one year for survival, freedom from major adverse events and cumulative adverse events. For open surgical repair subjects, females compared to males as follows: results at one year showed that females had a lower rate of cumulative adverse events (0.4 vs 0.8 with p=0.003), comparable freedom from major adverse events, and a slightly lower survival rate (87% vs 97% with p=0.07).

RESULTS

Tables 1 and 2 compare the subject characteristics and initial anuerysm diameter of the EXCLUDER Bifurcated Endoprosthesis and open surgical population, respectively.

Table 1: Comparison of Subject Characteristics

Characteristic	EXCLUDER Bifurcated Endoprosthesis (N = 235) N	(%)	Control (N = 99) N	(%)	p-Value
Average Age (range in years)	73.0 (48 - 91)		70.1 (51 - 87)		0.002
Gender:					
Male	204	87%	73	74%	
Female	31	13%	26	26%	0.004
Coronary Artery Disease	145	62%	53	54%	0.165
Arrhythmia	56	24%	21	21%	0.591
Valvular Heart Disease	18	8%	7	7%	0.852
Congestive Heart Failure	22	9%	8	8%	0.708
Stroke	26	11%	10	10%	0.818
Aneurysm Symptomatic	11	5%	15	15%	< 0.001
Inflammatory AAA	2	1%	1	1%	1.00
Family History of AAA	14	6%	9	9%	0.307
Other Concomitant Aneurysms	18	8%	13	13%	0.116
Peripheral Arterial Occlusive Disease	38	16%	14	14%	0.640
Prior Vascular Intervention	26	11%	10	10%	0.796
Long Term Use of Steroids	8	3%	1	1%	0.290
Thrombotic Event	17	7%	4	4%	0.332
COPD	62	26%	25	25%	0.830
Smoking History	208	89%	84	85%	0.357
Renal Dialysis	0	0%	0	0%	n/a
Paraplegia	0	0%	0	0%	n/a
Erectile Dysfunction (males only)	33	16%	10	14%	0.616
Hepatic Dysfunction	6	3%	1	1%	0.679
Bleeding Disorder	11	5%	1	1%	0.119
Cancer	59	25%	19	19%	0.243

Table 2: Aneurysm Diameter Distribution

Diameter Range	EXCLUDER Bifurcated Endoprosthesis (N = 235) N	(%)	Control (N = 98) N	(%)
< 30 mm	0	0%	0	0%
30 - 39 mm	0	0%	0	0%
40 - 49 mm	61	26%	15	15.3%
50 - 59 mm	109	46.4%	46	46.9%
60 - 69 mm	44	18.7%	21	21.4%
70 - 79 mm	15	6.4%	10	10.2%
80 - 89 mm	4	1.7%	5	5.1%
≥ 90 mm	2	0.9%	1	1.0%

Data gathered in Tables 3-13 were collected by either the Core Lab or the clinical study sites.Table 3 compares the safety and efficacy measures between the EXCLUDER Bifurcated Endoprosthesis and control subjects as reported by the clinical sites through the primary study end point of 12 months.

The study design is based on one-year safety and effectiveness outcomes. Subject follow-up is continuing and two-year data are also presented.

Table 3: Principal Safety and Efficacy Results

Outcome Measures	EXCLUDER Bifurcated Endoprosthesis (N = 235) N	(%)	Control (N=99) N	(%)	p-Value
Early (≤ 30 day) Mortality	3	1%	0	0%	p = 0.56
Early (≤ 30 day) Adverse Events	32	14%	56	57%	p < 0.0001
Early Conversion	0	0%	0	0%	n/a
Late Conversion	0	0%	0	0%	n/a
Rupture	0	0%	0	0%	n/a

Three conversions have occurred > 24 months postoperative due to aneurysm enlargement and proximal neck aneurysm enlargement.

Tables 4-11 describe results of the EXCLUDER Bifurcated Endoprosthesis subjects as reported by the Core Lab. Device performance factors analyzed by the Core Lab included device integrity (Table 4), device patency (Table 5), migration (Tables 6 and 7), and anuerysm exclusion (Tables 8-11). For device performance factors, more than one incident can occur to one subject and incidents are not necessarily viewed at every time point for one subject. Device integrity encompasses the structural findings of the wire-form via abdominal x-ray images at the corresponding follow-up timepoints.

Table 4: Device Integrity Assessment by Abdominal X-ray Imaging Data

Device Integrity: KUB	Discharge (N = 171) N	(%)	6 Months (N = 156) N	(%)	12 Months (N = 140) N	(%)	24 Months (N = 117) N	(%)
Subjects Free from Device Integrity Issues	145	85%	129	83%	120	86%	110	94%
Subjects with ≥ 1 Device Integrity Issue	26	15%	27	17%	20	14%	7	6%
- Fracture	1	0.6%	0	0%	0	0%	0	0%
- Kink	22	13%	18	12%	16	11%	4	3%
- Compression	4	2%	9	6%	4	3%	3	3%

Table 5: Occlusion or Narrowing of the Flow Channel by CT Imaging Data

Occlusion / Narrowing	1 Month (N = 212) N	(%)	6 Months (N = 193) N	(%)	12 Months (N = 185) N	(%)	24 Months (N = 148) N	(%)
EXCLUDER Bifurcated Endoprosthesis	3	1.5%	0	0%	2	1.1%	2	1.4%

Table 6: CT Findings – Trunk Migration

CT - Trunk Migration	6 Months (N = 171) N	(%)	12 Months (N = 175) N	(%)	24 Months (N = 144) N	(%)
Trunk Migration	5	3.0%	4	2.3%	2	1.4%

Table 7: Abdominal X-ray Findings – Component Migration

Abdominal X-ray - Component Migration	6 Months (N = 139) N	(%)	12 Months (N = 139) N	(%)	24 Months (N = 122) N	(%)
Component Migration	2	1.4%	1	1.0%	1	1.0%

Table 8: Endoleak Status According to Evaluation Interval

Type of Endoleak[1,2]	Evaluation Interval							
	1 Month (N = 180)		6 Months (N = 177)		12 Months (N = 156)		24 Months (N = 119)	
	N	(%)	N	(%)	N	(%)	N	(%)
Type I	7	4%	3	2%	2	1%	3	3%
Type II	21	12%	19	11%	19	12%	16	13%
Type III	0	0%	0	0%	0	0%	0	0%
Type IV	0	0%	0	0%	0	0%	0	0%
Indeterminate	11	6%	14	7%	6	4%	5	4%
Total	39	22%	36	20%	27	17%	24	20%

Table 9: Change in Aneurysm Size by Interval

Change in Aneurysm Size	1 Month to 6 Months (N = 182)		1 Month to 12 Months (N = 181)		1 Month to 24 Months (N = 146)	
	N	(%)	N	(%)	N	(%)
Decrease	18	10%	26	14%	28	19%
No Change	159	87%	142	78%	97	67%
Increase	5	3%	13	7%	21	14%

Table 10: Maximum Aneurysm Diameter and Endoleaks at 12 Months

Aneurysm Change from 1 to 12 Months*	N	Endoleak at 12 Months*		p-Value
		N	(%)	
Increase (≥ 5 mm)	10	4	40%	
No Change	118	19	16%	
Decrease (≤ 5 mm)	18	2	11%	
Total	146	25	17%	0.12

* Only includes subjects with interpretable films (endoleak) and measurements of aneurysm change from 1 to 12 months.

Table 11: Maximum Aneurysm Diameter and Endoleaks at 24 Months

Aneurysm Change from 1 to 24 Months*	N	Endoleak at 24 Months*		p-Value
		N	(%)	
Increase (≥ 5 mm)	15	7	47%	
No Change	74	10	14%	
Decrease (≤ 5 mm)	23	2	9%	
Total	112	19	17%	0.004

* Only includes subjects with interpretable films (endoleak) and measurements of aneurysm change from 1 month to 24 months.

Secondary interventions within the first and second year each were performed in 6% of the EXCLUDER Bifurcated Endoprostheses subjects as shown in Table 12. All interventions were catheter-based. Subjects may have a single intervention for an endoleak and an aneurysm enlargement.

Table 12: Interventions for Endoleak and Aneurysm Size Increases

Intervention	Post-procedure to 12 Months (N = 235)		> 12 Months to 24 Months (N = 203)	
	N	(%)	N	(%)
Number of Subjects with ≥ 1 Intervention	15	6%	12	6%
Treat an Endoleak:				
Embolization	16	7%	8	4%
Ligation	1	0%	0	0%
Conversion to open repair	0	0%	2*	1%
Treat an Aneurysm Increase:				
Embolization	0	0%	5	3%
Ligation	1	0%	0	0%
Conversion to open repair	0	0%	3*	1%

* Total of three conversions

As described in Table 13, treatment of AAA with EXCLUDER Bifurcated Endoprosthesis compared to the control group demonstrated significant benefits in recovery and quality of life measures.

Table 13: Secondary Outcomes by Treatment Group

Secondary Outcomes	EXCLUDER Bifurcated Endoprosthesis	Control	p-Value
Blood Loss (ml) Mean (range)	310 (50 - 2160)	1590 (100 - 7000)	< 0.0001
Procedure Transfusion (%)	14%	89%	< 0.0001
Procedure Time (minutes) Mean (range)	144 (51 - 320)	196 (67 - 420)	< 0.0001
ICU Stay (%)	24%	87%	< 0.0001
Hospital Length of Stay (days) Mean (range)	2 (1 - 11)	9.8 (3 - 114)	< 0.0001
Time to First Oral Intake (days) Mean (range)	0.5 (0 - 2.1)	2.6 (0.07 - 9.5)	< 0.0001
Time to Ambulation (days) Mean (range)	1.0 (0 - 5.0)	2.6 (0 - 18)	< 0.0001

CONCLUSIONS FROM CLINICAL STUDIES

As compared to conventional open surgery, the clinical benefits of the EXCLUDER Bifurcated Endoprosthesis are a lower rate of major complications, reduced blood loss and blood replacement volume, reduced need for an ICU stay, shorter hospitalization and faster return to normal activities. The risks include procedure- and/or device-related phenomenon, which include but are not limited to endoleaks and increase in aneurysm size.

1 White GH, May J, Waugh RC, et al. Type II and type IV endoleak: Toward a complete definition of blood flow in the sac after endoluminal AAA repair. J Endovasc Surg 5:305-309, 1998.

2 White GH, Yu W, May J, et al. Endoleak as a complication of endoluminal grafting of abdominal aortic aneurysms: Classification, incidence, diagnosis and management. J Endovasc Surg 4:152-168, 1997.

INDIVIDUALIZATION OF TREATMENT

These endoprostheses have not been studied in the following patient populations: traumatic, ruptured, or mycotic aneurysms; pseudoaneurysms resulting from previous graft or stent-graft placement; pregnant females; genetic connective tissue disease (e.g., Marfans or Ehlers-Danlos Syndromes); concomitant thoracic aortic or thoracoabdominal aneurysms.

HOW SUPPLIED

The EXCLUDER Extender Endoprosthesis is preloaded on a delivery catheter and supplied sterile and non-pyrogenic.

STORAGE AND HANDLING

Store in a cool dry place.

RECOMMENDED MATERIALS

- 0.035" (0.89 mm) 'super-stiff' guidewire, 145 cm or longer
- Aortic Extender:
  - 18 Fr x 30 cm introducer sheath
  - Large diameter, low pressure aortic balloon (Monitor balloon volumes and pressures as recommended in balloon catheter Instructions for Use)
- Iliac Extender:
  - 12 Fr (or larger) x 30 cm introducer sheath
  - PTA balloon catheters, 10 mm x 40 mm, 12 mm x 40 mm and 14 mm x 40 mm
- Angiographic radiopaque marker catheter
- Contrast medium
- Syringe
- Heparin and heparinized saline

TABLE 14: AORTIC EXTENDER SIZING GUIDE*

Intended Aortic Vessel Diameter (mm)	Aortic Extender Diameter[1] (mm)	Endoprosthesis Length (cm)	Recommended Introducer Sheath (Fr x mm)
19 - 21	23	3.3	18 x 30
22 - 23	26	3.3	18 x 30
24 - 26.5	28.5	3.3	18 x 30

[1] Recommended endoprosthesis oversizing relative to the vessel diameter is approximately 10-21%.

TABLE 15: ILIAC EXTENDER SIZING GUIDE*

Intended Iliac Vessel Diameter (mm)	Iliac Extender Diameter[1] (mm)	Endoprosthesis Length[2] (cm)	Recommended Introducer Sheath (Fr x mm)	Recommended Balloon Size (Proximal) (mm)	Recommended Balloon Size (Distal) (mm)
8 - 9	10	7	12 x 30	14	10
10 - 11	12	7	12 x 30	14	12
12 - 13.5	14.5	7	12 x 30	14	14

[1] Recommended endoprosthesis oversizing relative to the vessel diameter is approximately 7-25%.

[2] 7 cm long Iliac Extender provides a maximum extension of 4 cm when placed in the Trunk-Ipsilateral or Contralateral Leg Endoprosthesis.

* Note: All dimensions in Tables 14 and 15 are nominal.

DIRECTIONS FOR USE

Pre-Treatment Planning

- Determine accurate size of anatomy and proper size of Aortic and Iliac Extenders (Tables 14 and 15).
- Use high resolution non-contrast and contrast enhanced computerized tomography (CT) at ≤ 3 mm acquisition and reconstruction collimation.
- Use multiple view, digital subtraction angiography with a radiopaque marker catheter or spiral CT multiplanar reconstruction.
- For angiography, use correct imaging angulation (i.e., cranial-caudal, lateral-oblique) to accurately identify origin of branch vessel anatomy.
- Consider breath-hold technique to optimize image quality during digital subtraction angiography.

Anatomical Requirements

- For Aortic Extender Endoprosthesis: Proximal aortic neck angulation ≤ 60° with minimal thrombus and/or calcification
- For Iliac Extender Endoprosthesis: Non-aneurysmal iliac artery length ≥ 10 mm of appropriate diameter
- Ilio-femoral access vessel morphology should be compatible with vascular access techniques, devices and accessories

Arterial Access and Angiography

1. Following standard practices, access the vascular anatomy via a percutaneous diagnostic sheath and perform marker catheter digital subtraction angiography (AP, oblique and lateral views as necessary) to confirm the correct device component sizing, and deployment locations. Consider breath-hold technique to optimize image quality.
2. Following standard practices, perform percutaneous access and/or surgical exposure of the vessels selected to receive the Aortic Extender and Iliac Extender side introducer sheaths.
3. Following the manufacturer's instructions for use, advance a 0.035" (0.89 mm) 'superstiff' guidewire or acceptable equivalent to level of intended treatment.
4. Following the manufacturer's instructions for use, advance the 18 Fr diameter x 30 cm length or 12 Fr diameter x 30 cm length, introducer sheath over the guidewire, through the ilio-femoral anatomy, aortic aneurysm, and up to the level of the proximal aortic neck or iliac anatomy of intended treatment respectively.
5. Administer heparin according to standard practice.
6. Use standard heparinized saline, pressure flush system technique to prevent thrombus formation in the introducer sheaths.
7. Use an accurate radiopaque patient marking method to assure accurate device positioning and deployment locations.

Catheter Preparation

1. Use new, sterile gloves and minimize handling the endoprosthesis portion of the delivery catheters.
2. Remove the appropriately sized Extender Endoprosthesis delivery catheter from the packaging and examine for possible damage.
3. Remove protective packaging mandrel and packaging sheath(s) from the leading end of the delivery catheters (Figure 2A).
4. Flush with heparinized saline through the flushing port on the trailing end of the delivery catheter (Figure 2A).
5. Follow the manufacturer's instructions for use in size selection, preparation and use of aortic and iliac dilation balloons. Carefully inflate the balloon to avoid complications.

Aortic Extender Endoprosthesis Positioning and Deployment

1. Use fluoroscopic visualization for all guidewire, sheath and device catheter manipulations.
2. Advance the Aortic Extender Endoprosthesis delivery catheter over a 0.035" (0.89 mm) 'super-stiff' guidewire, through the 18 Fr x 30 cm long introducer sheath into the aorta, just proximal to the level of intended device positioning. **Warning: The catheter should not be rotated at any time to avoid possible catheter damage or premature deployment.**
3. While maintaining the delivery catheter in position, withdraw the introducer sheath back to the white shaft marker on the delivery catheter (Figure 2A).
4. Magnify and center the fluoroscopic image on the proximal Aortic Extender Endoprosthesis. Reposition the Endoprosthesis delivery catheter as necessary to position the proximal and distal radiopaque markers in appropriate position. The maximum recommended extension with each Aortic Extender component is approximately one-half of the Extender length inside (16 mm) and one-half, outside (16 mm), or proximal to the Trunk or Aortic Extender host component. The proximal three (3) and distal one (1) markers are visible relative to host device and anatomy pre and post deployment (Figures 1 and 2B).
5. If clinically acceptable, lower the patient's blood pressure to 60-70 mm Hg during Aortic Extender deployment and aortic balloon inflation to decrease blood flow and reduce the risk of endoprosthesis movement.
6. Stabilize the Extender delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
7. Loosen the deployment knob. Using fluoroscopy, confirm final device position and deploy the Aortic Extender using a steady and continuous pull of the deployment knob to release the endoprosthesis. Pull the deployment knob straight out from the catheter side-arm. Deployment initiates from the trailing end of the device toward the leading end of the device. **Warning: Once deployment is initiated, do not attempt to reposition the endoprosthesis.**
8. Use fluoroscopic guidance during the withdrawal of the delivery catheter to assure safe removal from, and to avoid catching on, the endoprosthesis.

9. Advance the aortic dilation balloon until it is centered relative to the endoprosthesis. Inflate and deflate the balloon quickly with dilute contrast solution to seat the Aortic Extender Endoprosthesis. Follow the manufacturer's recommended method for size selection, preparation and use of aortic dilation balloons. Carefully inflate the balloon to avoid complications.
10. Use fluoroscopic guidance to ensure the balloon is completely deflated and to assure safe removal from, and to avoid catching on, the endoprosthesis.

Iliac Extender Endoprosthesis Positioning and Deployment

1. Use fluoroscopic visualization for all guidewire, sheath and device catheter manipulations.
2. Advance the Iliac Extender Endoprosthesis delivery catheter into the distal end of the host device, via the 12 Fr x 30 cm length introducer sheath. **Warning: Do not attempt to rotate the catheter at any point to avoid catheter breakage or premature deployment.**
3. For maximum extension (4 cm), align the radiopaque marker at the iliac (distal) end of the host device with the middle marker of the Extender component (Figures 2C and 3).
4. While maintaining the delivery catheter in position, withdraw the introducer sheath back to the white shaft marker on the delivery catheter (Figure 2A).
5. Stabilize the Iliac Extender delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
6. Loosen the deployment knob. Confirm final device position. Using fluoroscopy, deploy the Iliac Extender Endoprosthesis by using a steady, continuous pull of the deployment knob to release the endoprosthesis. Pull the deployment knob straight out from the catheter side-arm. The device deploys from the leading (proximal) end toward the trailing (distal) end. **Warning: Once deployment is initiated, do not attempt to reposition the endoprosthesis.**
7. Use fluoroscopic guidance during the withdrawal of the delivery catheter to assure safe removal from, and avoid catching on, the endoprosthesis.
8. Advance and inflate an appropriate size PTA balloon catheter to seat the proximal overlap end and the distal end of the Iliac Extender Endoprosthesis. Follow the manufacturer's recommended method for size selection, preparation and use of PTA balloons. Carefully inflate the balloon to avoid complications.
9. Use fluoroscopic guidance to ensure the balloon is completely deflated and to assure safe removal from, and to avoid catching on, the endoprosthesis.

Completion of the Procedure

1. Perform extended imaging angiography to confirm exclusion of the aneurysm. Consider breath-hold technique to optimize image quality.
2. Close arterial access according to standard practice.
3. Follow-up patients as necessary to provide proper surveillance of the long-term performance of the endoprosthesis, procedure and status of the aneurysm. Annual CT's and various views of x-rays may be used for such surveillance.
4. The EXCLUDER Bifurcated Endoprosthesis has been determined to be MR safe. That is, the EXCLUDER Bifurcated Endoprosthesis when present in a patient or other individual undergoing an MRI procedure or in the MR environment at 1.5 Tesla or less will not present an additional hazard or risk, but may affect image quality depending on the pulse sequence that is used and the imaging area of interest evaluated.

   Safety information for magnetic resonance imaging (MRI) procedures (i.e., imaging, angiography, functional imaging, and spectroscopy) pertains to the use of shielded MRI systems with static magnetic fields of 1.5 Tesla or less, gradient magnetic fields of 20 Tesla/second or less, and a whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of imaging. The effects of performing MRI procedures using MR systems with static magnetic fields greater than 1.5 Tesla and other conditions have not been determined.

DEFINITIONS

Use By

Attention, See Instructions for Use

Do Not Reuse

REF Catalogue Number

LOT Batch Code

STERILE

Contents sterile unless package has been opened or damaged.

STERILE EO

Contents sterile unless enclosed package has been opened or damaged.
Sterilized by ethylene oxide.

Store in a cool dry place

10LS1887.00.FDA03

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